UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC.,

Plaintiff,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Defendant.

Case No.: C 10-2037-LHK (PSG)

ORDER GRANTING-IN-PART AND DENYING-IN-PART PLAINTIFF'S MOTION TO COMPEL COMPLIANCE WITH PATENT LOCAL RULE 3-1

On December 7, 2010, the parties appeared before the undersigned for hearing on Plaintiff Genentech, Inc.'s ("Genentech") Motion to Compel Compliance with Patent Local Rule 3-1. Genentech seeks further disclosure by Defendant The Trustees of the University of Pennsylvania ("the University") of its infringement contentions regarding the administration of Genentech's breast cancer therapeutic drug Herceptin®. Genentech's motion raises a novel question regarding the application of Patent Local Rule 3-1 to method claims directed to the administration of a therapeutic compound. Based on the briefs and arguments submitted,

IT IS HEREBY ORDERED that Plaintiff's motion is GRANTED-IN-PART AND DENIED-IN-PART.

I. BACKGROUND

The University is the assignee of United States Patent No. 6,733,752 ("the '752 Patent").

The '752 Patent is entitled "Prevention of Tumors with Monoclonal Antibodies against NEU." (*See* Complaint for Declaratory Judgment, filed herein on May 11, 2010 ("Complaint"), Exh. A.) Claim 1 of the '752 Patent claims "a method of inhibiting development into breast cancer cells of breast cells that overexpress p185 in an individual in need of such inhibition," comprising various steps. (*Id*, col. 8, lines 49-51.) These steps include the administration of an antibody "in sufficient amount to down regulate the overexpressed p185 and inhibit the development of said breast cells that overexpress p185 into breast cancer cells." (*Id*, col. 8, lines 51-57.)

On September 7, 2010, pursuant to Patent Local Rule 3-1(b), the University served its "Initial Disclosure of Asserted Claims and Infringement Contentions" ("Infringement Contentions"). In its Infringement Contentions, the University identifies the "Accused Instrumentality" as the method of administering Herceptin® to "specific classes" of patients under the indications in the FDA-approved package insert for the drug. (*See* Fujiyama Decl.,[1] Exh. 1, 2:5-10.) Pursuant to Patent Local Rule 3-1(c), the University further contents that these "specific classes" include any "human who has been diagnosed with metastatic disease and after removal of human epidermal growth factor 2 protein (HER) overexpressing tumor." (*See* Fujiyama Decl., Exh. 1 (at Exh. A).) The University also contends that the accused method administers Herceptin® "in sufficient quantity to down regulate the overexpressed p185 and inhibit the development of said breast cells that overexpress p185 into breast cancer cells" by administering Herceptin® "consistent with dosing and guidelines" included FDA-approved package insert. (*Ibid*.)

After reviewing the Infringement Contentions, and an unsuccessful effort to meet and confer with the University, Genentech now challenges the sufficiency of the University's Infringement Contentions. In particular, Genentech alleges that the University had failed to meet an obligation to inform Genentech as to (1) the particular patients receiving Herceptin® that fall within the University's infringement theory, (2) where within the accused method breast cells overexpress p185, and (3) where within the accused method overexpressed p185 is down regulated. The

[1] As used herein, "Fujiyama Decl." refers to the Declaration of Sandra S. Fujiyama in Support of (1) Motion to Compel Compliance by Defendant with Patent Local Rule 3-1 and (2) Motion for Stay of Plaintiff's Disclosures under Patent Local Rules 3-3 and 3-4 Pending Full Compliance and Responses by Defendant, filed on September 17, 2010 as part of docket no. 21.

University denies any such obligation, arguing that its Infringement Contentions satisfy both the letter and spirit behind Rule 3-1.

II. DISCUSSION.

For over a decade, the Patent Local Rules of this District have provided a "streamlined" mechanism to replace the "series of interrogatories that accused infringers would likely have propounded" in its absence. *See FusionArc, Inc. v. Solidus Networks, Inc.,* No. C 06-06760 RMW (RS), 2007 WL 1052900, *2 (N.D. Cal. Apr. 5, 2007). As with similar local patent rules since adopted by other federal district courts, this District's local patent rules "require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Atmel Corp. v. Information Storage Devices*, C 95-1987 FMS, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). These rules "provide structure to discovery and enable the parties to move efficiently toward claim construction and the eventual resolution of their dispute." *American Video Graphics, L.P. v. Electronic Arts, Inc.*, 359 F. Supp. 2d 558, 560 (E.D. Tex. 2005); *cf. Network Caching Technology, LLC. v. Novell, Inc.*, No. C 01-2079 VRW, 2002 WL 32126128, at *5 (N.D. Cal. Aug. 13, 2002) (noting that the infringement contention requirement of Patent Local Rule 3-1 are designed to "facilitate discovery").

The requirements for disclosure of a patentee's infringement theories are set forth in Patent Local Rule 3-1. In particular, Patent Local Rule 3-1(b) requires a party claiming patent infringement to identify:

> "Separately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality ("Accused Instrumentality") of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product, device, and apparatus shall be identified by name or model number, if known. Each method or process shall be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process."

Patent Local Rule 3-1(c) further requires a party claiming patent infringement to serve:

> "A chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function."

These rules do not, as is sometimes misunderstood, "require the disclosure of specific evidence nor do they require a plaintiff to prove its infringement case." *Whipstock Services, Inc. v. Schlumberger*

Oilfield Servs., No. 6:09-cv-113, 2010 WL 143720 (E.D. Tex. Jan. 8, 2010), at *1. But a patentee must nevertheless disclose what in each Accused Instrumentality it contends practices each and every limitation of each asserted claim to the extent appropriate information is reasonably available to it. *Cf. Fusionarc, Inc. v. Solidus Networks, Inc.*, 2007 WL 1052900, at *1 (denying motion to strike infringement contentions where "the record demonstrates that [patentee] FusionArc's [infringement contentions] reasonably disclose all of the information it presently possesses").

Where the Accused Instrumentality includes computer software based upon source code made available to the patentee, patentees must provide "pinpoint citations" to the code identifying the location of each limitation. *See Big Baboon Corp. v. Dell, Inc.*, No. CV 09-01198 SVW (Ssx), --- F.Supp.2d ---, 2010 WL 2766327) at *3 (C.D. Cal. July 2, 2010); *American Video Graphics, L.P. v. Elec. Arts, Inc.*, 359 F.Supp.2d 558, 561 (E.D.Tex. 2005); and *Diagnostic Systems Corp. v. Symantec Corp., et al.*, Nos. SACV 06-1211 DOC (ANx), SACV 07-960 DOC (ANx), 2009 WL 1607717, at *6 (C.D.Cal. June 5, 2009). This Court has gone further, holding that even when no source code has been made available by the defendant, "reverse engineering or its equivalent" is required for at least one of the accused products to identify where each limitation of each claim is located. *See Network Caching*, 2003 WL 21699799, at *5. The parties have not cited–and the Court has not found–any case suggesting that this principle of disclosure of all information reasonably available to a patentee is limited to the context of computer software. To the contrary, the plain language of Rule 3-1 makes no such distinction, requiring that all patentees makes such disclosures, whether the asserted patent is directed towards computer software, methods of administering therapeutics, or anything else "under the sun." *See Diamond v. Chakrabarty.* 447 U.S. 303, 309 (1980).

Applying these principles to the present dispute, Genentech's arguments both stand and fall. With respect to the first deficiency asserted by Genentech, Genentech challenges the University's failure to specify whether its theory of infringement encompasses administration of Herceptin® to patients with lymph node positive HER2 overexpressing breast cancer, patients that are lymph node negative, estrogen receptor negative patients or progesterone negative patients. But the University has clearly stated that it accuses the administration of Herceptin® to all patients who have "not been

diagnosed with metastatic disease after removal of human epidermal growth factor 2 protein (HER) overexpressing tumor(s)." This adequately provides notice to Genentech and the Court as to the scope of what patients fall within the scope of the University's infringement theory. While the University might have elected to accuse one or more of the narrower sub-categories of patients identified by Genentech, nothing in Rule 3-1 requires it to do so.[2]

In contrast, with respect to the Genentech's second and third asserted deficiencies, the University fails to address information reasonably available to it. While Claim 1 requires the University to prove that the accused method results in down-regulation of the overexpressed p185, the University's Infringement Contentions identify no step in that method where down-regulation occurs. Instead, the University simply points to "[t]he therapeutic administration of Trastuzumab[3] in the relevant population" according to the guidelines in the package insert as satisfying this limitation. Because the FDA-approved packaging insert for Herceptin®, as well as publications describing the clinical trials for antibodies including Hercerptin®, explicitly identify a specific mechanism (antibody-dependent-cellular-cytotoxicity, or ADCC) for inhibiting the proliferation of cells that overexpress the HER2 protein within the p185 class, the University's contentions should at a minimum address whether this mechanism falls within its infringement theory.[4] Similarly, in addressing Claim 1's requirement regarding inhibition of "the development of said breast cells that overexpress p185 into breast cancer cells," the University once again points to the nothing more the administration of the therapeutic according to the package insert's guidelines. This says nothing about where in the accused method the University contends the "breast cells overexpressing p185" are found. The published literature available to the University, including one article authored by the named inventors of the asserted patent, identifies "disseminated tumor cells," "disseminated cancer cells," and "cancer stem cells" as possible candidates. The University's contentions should address

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[2] Of course, having elected to include this broader class of patients in its Infringement Contentions, the University is now so bound, absent relief pursuant to Patent Local Rule 3-6 or as otherwise authorized by the Court.

[3] Trastuzumab is the generic name for Herceptin®

[4] *Cf. Bender Maxim Integrated Prods., Inc.*, No. C 09-01152 SI,2010 WL 1135762, at *2 (N.D. Cal. Mar. 22, 2010) (holding that accused infringer should not be " asked to assume that certain elements are present in the accused product").

whether its theory infringement is directed to these cells, more than just these cells, or other cells altogether.

III. CONCLUSION

Within fourteen days of this order, the University shall supplement its contentions regarding the "breast cells overexpressing p185" and "down regulate" limitations of the '752 patent. All other relief requested in Genentech's motion is denied.

Dated: *December 13, 2010*

PAUL S. GREWAL
United States Magistrate Judge